Soleil Infusion: Compliance Implementation Guide

February 9, 2026

1. Executive Summary

This Compliance Implementation Guide provides a practical roadmap for establishing and maintaining regulatory compliance for Soleil Infusion. The guide is based on the Maryland Concierge Infusion Clinic Compliance Checklist and White Paper provided, as well as applicable Maryland statutes and COMAR regulations. It is designed to ensure that Soleil Infusion operates within the bounds of all applicable laws and regulations, minimizing legal and financial risk while providing safe, high-quality patient care.

Compliance is not a one-time task but an ongoing commitment. This guide outlines the initial setup requirements as well as the ongoing compliance calendar that must be followed to maintain good standing with regulatory authorities and protect the business from liability.

2. Regulatory Scoping and Facility Classification

2.1. Defining the Service Model

Soleil Infusion will operate as a **physician-supervised, nurse practitioner-administered outpatient IV infusion clinic**. The services will be limited to:

- On-site IV infusions (no dispensing of take-home medications).
- Non-chemotherapeutic, non-narcotic infusions (vitamins, minerals, antioxidants, peptides, iron).
- No sedation beyond minimal anxiolysis (if any).
- No in-house laboratory testing beyond waived point-of-care tests (if any).
- No mobile or home infusion services at launch (to be evaluated in Phase 2).

2.2. Facility Classification Determination

Based on the service model described above, Soleil Infusion will operate as a **professional practice (physician/NP outpatient office)** and will **not require separate facility licensure** from the Maryland Office of Health Care Quality (OHCQ). This determination is based on the following:

- No surgery or office-based anesthesia beyond minimal sedation.
- No on-site compounding of sterile preparations (all compounded products will be sourced from Voshell's Pharmacy, a licensed 503B outsourcing facility).

- No dispensing of take-home medications (administration only).
- No enrollment as a Medicaid provider at launch (cash-pay model).
- No non-waived laboratory testing at launch.

Action Item: A short "regulatory classification memo" will be prepared and maintained in the compliance file, documenting this determination and the rationale. This memo will be reviewed and updated if services change.

3. Governance and Professional Responsibility

3.1. Medical Director

A board-certified physician will be designated as the Medical Director. The Medical Director's responsibilities will include:

- Approving all clinical protocols, SOPs, and informed consent documents.
- Providing oversight of all clinical operations.
- Reviewing all adverse events and incident reports.
- Ensuring compliance with all applicable regulations.
- Being available for consultation and emergency escalation.

Action Item: A formal Medical Director Agreement will be executed, clearly outlining these responsibilities, availability standards, and compensation.

3.2. Clinical Governance Charter

A written Clinical Governance Charter will be created, defining:

- The scope of services offered.
- The roles and responsibilities of each clinical staff member (Medical Director, NP, RN).
- The process for ordering, administering, and monitoring infusions.
- The escalation pathways for adverse events and emergencies.
- The quality assurance and performance improvement (QAPI) process.

Action Item: The Clinical Governance Charter will be drafted by the Medical Director and approved by the Founder.

3.3. Compliance Program

A formal Compliance Program will be established, including:

- **Compliance Officer**: The Founder will serve as the initial Compliance Officer.

- **Reporting Line**: The Compliance Officer will report directly to the Medical Director and the Board (if applicable).
- **Annual Workplan**: An annual compliance workplan will be developed, outlining key compliance activities and audit schedules.
- **Audit Schedule**: Regular audits will be conducted to ensure compliance with clinical protocols, billing practices (if applicable), and regulatory requirements.

Action Item: A Compliance Program Charter will be drafted and approved.

4. Staffing, Credentialing, and Scope-of-Practice

4.1. Licensing and Credentialing

All clinical staff (Medical Director, NP, RN) will be required to maintain active Maryland licenses. The following credentialing process will be followed:

- **Primary Source Verification**: Licenses will be verified directly with the Maryland Board of Physicians and Board of Nursing.
- **Renewal Tracking**: A system will be implemented to track license renewal dates and ensure timely renewals.
- **Credentialing File**: A credentialing file will be maintained for each clinician, including:
    - Copy of current license.
    - Copy of national certification (e.g., NP certification).
    - Copy of DEA registration (if applicable).
    - Proof of BLS/ACLS certification.
    - Background check results.
    - References.
    - Training records.

Action Item: A Credentialing Checklist will be created and used for all new hires.

4.2. Nurse Practitioner Scope of Practice

The NP will be responsible for patient consultations, ordering infusions, administering infusions, and managing day-to-day clinical operations. The NP's scope of practice will be clearly defined and aligned with Maryland NP scope, certification, and prescriptive authority. If the NP is newly certified, the mentorship requirements under Md. Code Ann., Health Occ. § 8-302.1 will be followed.

Action Item: An NP Job Description and Scope of Practice document will be created and signed by the NP and Medical Director.

4.3. Staff Training

All clinical staff will receive comprehensive training on:

- All clinical protocols and SOPs.
- Infusion reactions and adverse event management (anaphylaxis, vasovagal reactions, infiltration/extravasation).
- Emergency procedures and escalation pathways.
- Infection control and aseptic technique.
- HIPAA privacy and security.
- OSHA Bloodborne Pathogens.

Action Item: A Staff Training Checklist will be created, and all training will be documented.

5. Facility, Environment of Care, and Patient Safety

5.1. Zoning and ADA Compliance

The facility at 801 Landmark Drive will be verified for compliance with local zoning and occupancy requirements. The facility will be designed to be ADA-compliant, with accessible care areas and restroom access.

Action Item: Obtain written confirmation of zoning compliance from local authorities.

5.2. Infection Control

A comprehensive Infection Prevention Program will be implemented, including:

- Hand hygiene stations at all points of care.
- Designated medication preparation area.
- Separation of clean and dirty workflows.
- Environmental cleaning protocols.
- Aseptic technique for all IV insertions and medication preparation.
- Staff immunization and exposure management.

Action Item: An Infection Control Policy will be drafted and approved by the Medical Director.

5.3. Emergency Readiness

The facility will be equipped with all necessary emergency equipment and supplies, including:

- Automated External Defibrillator (AED).
- Oxygen and suction.

- Epinephrine and other emergency medications (antihistamines, corticosteroids, bronchodilators).
- Crash cart or emergency kit.
- IV fluids and supplies.

A written Emergency Response Plan will be created, and all staff will be trained on emergency procedures. Mock emergency drills will be conducted quarterly.

Action Item: An Emergency Response Plan will be drafted and approved by the Medical Director.

5.4. Equipment Management

All medical equipment will be maintained according to manufacturer specifications. Maintenance logs will be kept, and biomedical inspections will be scheduled as needed.

Action Item: An Equipment Maintenance Log will be created and maintained.

5.5. Medication Storage

A refrigeration unit will be used for medications requiring cold chain storage. Daily temperature logs will be maintained, and an excursion response plan will be in place.

Action Item: A Temperature Monitoring Log and Excursion Response Plan will be created.

5.6. Sharps Safety

Safety-engineered sharps devices will be used wherever feasible. Sharps containers will be placed at all points of use. A Needlestick Response Protocol and Exposure Control Plan will be in place.

Action Item: A Sharps Safety Policy and Needlestick Response Protocol will be drafted.

6. Medication Management

6.1. Procurement

All medications and compounded sterile preparations will be procured from properly licensed and authorized trading partners. Voshell's Pharmacy will be the primary supplier of compounded sterile preparations. Vendor due diligence will be conducted, and all vendor licenses will be verified.

Action Item: A Vendor Due Diligence Checklist will be created and used for all new vendors.

6.2. Inventory Controls

A robust inventory management system will be implemented, including:

- Lot and expiration date tracking.
- Recall workflow.
- Separation of patient-specific and clinic stock.
- Controlled access to medication storage areas.

Action Item: An Inventory Management Policy will be drafted.

6.3. Medication Preparation

All medications will be prepared according to established protocols. If any immediate-use preparations are made, they will be aligned with USP <797> standards. All compounded sterile preparations will be sourced from Voshell's Pharmacy, which will maintain certificates of analysis and ensure proper labeling and beyond-use dating (BUD).

Action Item: A Medication Preparation Policy will be drafted.

6.4. Administration Protocols

Detailed administration protocols will be created for each type of infusion, including:

- Patient assessment before infusion (contraindications, allergies, vital signs).
- Dosing and infusion rates.
- Vitals monitoring schedule.
- Observation period.
- Discharge criteria.

Action Item: Infusion Protocols will be drafted for each service offering and approved by the Medical Director.

7. Informed Consent, Patient Communications, and Risk Management

7.1. Informed Consent

A standardized informed consent process will be implemented for all infusions. The informed consent document will include:

- Diagnosis/indication or wellness objective.

- Material risks (hypersensitivity, extravasation, iron-related reactions, etc.).
- Reasonable alternatives (including no treatment).
- Off-label use disclosure (for peptide therapies and other off-label uses).
- Financial terms (pricing, refund policy, HSA/FSA eligibility).
- Consent for emergency transfer and external sharing of records.

Action Item: Informed Consent Templates will be drafted for each service category and approved by the Medical Director.

7.2. Adverse Event Management

A formal Adverse Event Disclosure Policy will be created, defining:

- When the Medical Director must be notified.
- How adverse events will be documented.
- The root-cause analysis and corrective action process.

Action Item: An Adverse Event Policy will be drafted.

7.3. Refund and Cancellation Policies

Clear refund and cancellation policies will be established and communicated to all clients.

Action Item: Refund and Cancellation Policies will be drafted and posted on the website.

8. Documentation, Privacy, and Record Retention

8.1. Electronic Health Records (EHR)

An EHR system will be implemented with authenticated entries, audit trails, and role-based access.

Action Item: Select and implement an EHR system.

8.2. HIPAA Compliance

A comprehensive HIPAA Compliance Program will be implemented, including:

- Designation of a Privacy and Security Officer (Compliance Officer).
- HIPAA policies and procedures.
- Business Associate Agreements (BAAs) with all vendors who have access to PHI.
- Breach response plan.
- Annual HIPAA training for all staff.

Action Item: A HIPAA Compliance Manual will be drafted, and BAAs will be executed with all applicable vendors.

8.3. Record Retention

Medical records will be retained for a minimum of 7 years for adult patients (longer for minors), in compliance with Maryland law.

Action Item: A Record Retention Policy will be drafted.

9. Employment, OSHA/MOSH, and Workers' Compensation

9.1. Workers' Compensation

Maryland workers' compensation coverage will be obtained before the first employee is hired. Required notices will be posted, and all injuries will be tracked.

Action Item: Obtain workers' compensation insurance.

9.2. OSHA/MOSH Programs

The following OSHA/MOSH programs will be implemented:

- **Bloodborne Pathogens Program** (29 CFR 1910.1030): Exposure control plan, training, HBV vaccination, post-exposure evaluation.
- **Hazard Communication Program**: SDS inventory for all chemicals and disinfectants.
- **Personal Protective Equipment (PPE) Program**: Ensuring appropriate PPE is available and used.

Action Item: OSHA/MOSH Program Manuals will be drafted.

10. Insurance Program

A comprehensive insurance portfolio will be secured, including:

- **Professional Liability (Medical Malpractice)**: For the entity and each clinician (MD, NP, RN).
- **General Liability**: Premises/operations and product liability.
- **Property Coverage**: For build-out and equipment; business interruption.
- **Workers' Compensation and Employers' Liability**.
- **Cyber Liability**: HIPAA/privacy, including ransomware and business interruption.
- **Employment Practices Liability (EPLI)**.

Action Item: Obtain quotes and secure all insurance policies before opening.

11. Ongoing Compliance Calendar

A structured compliance calendar will be followed to ensure ongoing compliance:

Frequency	Tasks
Daily	Review fridge/freezer temperature logs; check emergency kit seal; spot-check infusion documentation completeness.
Weekly	Inventory expiration checks; sharps container status; cleaning audits.
Monthly	Medication reconciliation/audit; adverse event/near miss review; staff competency refreshers as needed.
Quarterly	QAPI meeting; chart audits; policy review for high-risk areas (consent, meds, emergency response); mock emergency drill.
Annually	HIPAA + OSHA training; insurance renewal review; emergency drills; compliance workplan refresh; vendor re-credentialing.
Biennial or as required	CLIA renewal (if applicable); license renewals per board cycles; review updated COMAR changes.
Every 5 years	Maryland physician dispensing permit renewal (if applicable).

Action Item: A Compliance Calendar will be created and integrated into the clinic's operational calendar.

12. Key Maryland Authorities and Resources

The following Maryland statutes and COMAR regulations will be consulted and referenced as needed:

- Maryland NP scope/dispensing rules (COMAR 10.27.07)
- Maryland NP mentorship requirement (Md. Code Ann., Health Occ. § 8-302.1)

- Physician dispensing permit rules (COMAR 10.32.23; COMAR 10.13.01.04)
- Maryland medical record confidentiality/retention (Health–Gen. §§ 4-301 et seq.; § 4-403)
- Maryland Health Care Malpractice Claims Act (Md. Code Ann., Cts. & Jud. Proc. §§ 3-2A-01 et seq.)
- Maryland special medical waste rules (COMAR 26.13.12)
- FDA compounding (503A/503B) and DSCSA trading partner guidance

13. Conclusion

Compliance is the foundation of a safe, sustainable, and legally defensible IV infusion practice. By following this Compliance Implementation Guide and adhering to the ongoing compliance calendar, Soleil Infusion will minimize legal and financial risk, protect patients, and build a reputation for quality and integrity. This guide should be reviewed and updated regularly to reflect changes in regulations, services, and best practices.